July 17, 2002

MEMORANDUM:

SUBJECT: **Lindane** (009001): **Reregistration Case** 0315. **Addendum to the Revised Chemistry and HED Chapters (DP Barcode: D279259 & D283643) for the Lindane Reregistration Eligibility Document (RED).** DP Barcode: D284183.

FROM: Thurston G. Morton, Chemist
                            Reregistration Branch 4
                            Health Effects Division (7509C)

THROUGH: Susan V. Hummel, Branch Senior Scientist
                            Reregistration Branch 4
                            Health Effects Division (7509C)

TO: Rebecca Daiss, Risk Assessor
                            Reregistration Branch 4
                            Health Effects Division (7509C)

                                    And

                            Mark Howard/Betty Shackleford
                            Reregistration Branch 3
                            Special Review & Reregistration Division (7508C)

This memorandum serves to update the Tolerance Tables contained in the Product and Residue Chemistry Chapter (T. Morton, 12/11/01, D279259) and the HED Risk Assessment (B. Daiss, 6/13/02, D283643) by amending the tolerances which were listed as TBD (to be determined). Recommended tolerance levels for lindane, *per se*, in cereal grains are derived from the wheat magnitude of the residue study (T. Morton, 8/30/00, D259318). Tolerances will be re-evaluated when the required nature of the residue study is submitted.

<u>EXECUTIVE SUMMARY</u>:

<u>Residue Chemistry</u>

- A new nature of the residue study is required for application of lindane as a seed treatment to a cereal grain.

- If the HED Metabolism Assessment Review Committee determines the residues of concern to include metabolites in addition to lindane, then additional crop field trial data, magnitude of the residue in poultry and cattle, and processing studies are required. In addition, an adequate residue analytical method and storage stability data will be required.

cc : Chem F, Chron F. Morton

RDI: SVH:7/17/02

TM, Thurston Morton, Rm. 816D CM2, 305-6691, mail code 7509C

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of lindane in/on raw agricultural and animal commodities are established under 40 CFR §180.133 and expressed in terms of residues of lindane *per se* [gamma isomer of benzene hexachloride]. The residue definition for lindane is misleading and should be amended as follows to harmonize with IUPAC nomenclature: gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane. Plant commodity tolerances for lindane were originally established based on registered uses which included preplant soil application, foliar applications, and seed treatments. Animal commodity tolerances were established based on uses which included direct livestock animal treatment as well as animal premise treatment. Refer to Table B for a list of established and proposed lindane tolerances.

The only food/feed use of lindane which is being supported for reregistration is seed treatment on cereal grains (excluding rice and wild rice).

At this time, lindane tolerances are being reassessed in terms of lindane, *per se*. The nature of the residue in plants and animals must be adequately elucidated, and HED's MARC must determine the terminal residues of concern. The tolerances will be re-evaluated once an adequate nature of the residue study in plants is submitted.

The listing of lindane tolerances under 40 CFR §180.133 should be subdivided into parts (a), (b), (c), and (d). Part (a) should be reserved for commodities with permanent tolerances, part (b) for Section 18 emergency exemptions, part (c) for tolerances with regional registrations, and part (d) for indirect or inadvertent residues.

Tolerances Listed Under 40 CFR §180.133:

Following resolutions of residue chemistry data deficiencies specified in this Residue Chemistry Science Chapter, a statement in 40 CFR §180.133 should be added to specify that the established tolerances result from seed treatment only.

The established tolerances for the following commodities should be revoked because no registrants have committed to support their uses: apples, apricots, asparagus, avocados, broccoli, Brussels sprouts, cabbage, cauliflower, celery, cherry, collards, cucumbers, eggplants, grapes, guavas, kale, kohlrabi, lettuce, mangoes, melons, mushrooms, mustard greens, nectarines, okra, onions (dry bulb only), peaches, pears, pecans, peppers, pineapple, plums (fresh prunes), pumpkins, quinces, radish, spinach, squash, strawberries, summer squash, swiss chard, and tomatoes.

Tolerances To Be Proposed Under 40 CFR §180.133:

Tolerances for lindane, *per se*, need to be established for: barley, grain; barley, hay; barley, straw; corn, grain; corn, forage; corn, stover; oat, grain; oat, forage; oat, hay; oat, straw; rye, grain; rye, forage; rye, straw; sorghum, grain; sorghum, forage;

sorghum, stover; wheat, grain; wheat, forage; wheat, hay; and wheat, straw. In addition, tolerances for lindane, *per se*, need to be established for meat byproducts of cattle, goat, horse, and sheep; fat of cattle, goat, hog, horse, and sheep; milk; and fat of poultry. The remaining livestock tissues (meat and meat byproducts of hog and poultry; and eggs are 40 CFR 180.6(a)(3) [no reasonable expectation of finding finite lindane residues] provided the HED MARC determines lindane, per se, is the only residue of concern. The tolerances for lindane, *per se*, will be re-evaluated once adequate nature of the residue data in plants are submitted.

Pending Tolerance Petitions:

In 1993, CIEL proposed to delete all food/feed uses except seed treatment. Concomitantly, CIEL proposed to establish tolerances of 0.1 ppm for residues of lindane *per se* in/on several RACs as a result of seed treatment. In an initial Agency review (DP Barcode D213401, 10/31/95, S. Funk) of available residue data reflecting seed treatment, the Agency concluded that the proposed tolerances were adequate in some instances and inadequate or non-acceptable in others. In those instances where the proposed tolerances were deemed inadequate, the reviewer proposed values that HED would consider as appropriate.

In 1998, CIEL submitted a petition, PP#9F05057, for the establishment of time-limited tolerances for residues of lindane *per se* in/on several commodities resulting from seed treatment. The Agency review (DP Barcodes D254236, 8/30/00, T. Morton) of these tolerance proposals concluded that tolerances could not be established until an acceptable nature of the residue study in plants was submitted. At this time, tolerance levels for lindane, *per se*, are being recommended for cereal grains. These tolerances will be re-evaluated once adequate nature of the residue data are submitted.

The registrants have also submitted PP#9F6022, (D269388, T. Morton, 5/10/01) for the establishment of tolerances on lindane *per se* in/on canola for which seed treatment is being proposed. Tolerances cannot be established until adequate nature of the residue data in plants are submitted.

Table B.   Tolerance Reassessment Summary for Lindane.

Commodity	Tolerance Listed Under 40 CFR (ppm)	Reassessed Tolerance (ppm)	Comment *[Correct Commodity Definition]*
Tolerance Listed Under 40 CFR §180.133			
Apples	1	Revoke	Not being supported for reregistration.
Apricots	1	Revoke	Not being supported for reregistration.
Asparagus	1	Revoke	Not being supported for reregistration.
Avocados	1	Revoke	Not being supported for reregistration.
Broccoli	1	Revoke	Not being supported for reregistration.
Brussels sprouts	1	Revoke	Not being supported for reregistration.
Cabbage	1	Revoke	Not being supported for reregistration.
Cauliflower	1	Revoke	Not being supported for reregistration.
Lettuce	3	Revoke	Not being supported for reregistration.
Spinach	1	Revoke	Not being supported for reregistration.
Celery	1	Revoke	Not being supported for reregistration.
Collards	1	Revoke	Not being supported for reregistration.
Kale	1	Revoke	Not being supported for reregistration.
Kohlrabi	1	Revoke	Not being supported for reregistration.
Mustard greens	1	Revoke	Not being supported for reregistration.
Swiss chard	1	Revoke	Not being supported for reregistration.
Cherry	1	Revoke	Not being supported for reregistration.
Cucumbers	3	Revoke	Not being supported for reregistration.
Eggplants	1	Revoke	Not being supported for reregistration.
Fat of meat from cattle, goats, horses, and sheep	7	0.05	The Agency will re-calculate the maximum theoretical dietary burden for livestock animals and re-evaluate the adequacy of the available animal feeding studies when the required nature of the residue data in plants have been received and evaluated. / ***Cattle, fat; goat, fat; horse, fat; sheep, fat***
Fat of meat from hogs	4	0.01	***Hog, fat***
Grapes	1	Revoke	Not being supported for reregistration.
Guavas	1	Revoke	Not being supported for reregistration.
Mangoes	1	Revoke	Not being supported for reregistration.
Melons	3	Revoke	Not being supported for reregistration.
Mushrooms	3	Revoke	Not being supported for reregistration.
Nectarines	1	Revoke	Not being supported for reregistration.
Okra	1	Revoke	Not being supported for reregistration.
Onions (dry bulb only)	1	Revoke	Not being supported for reregistration.
Peaches	1	Revoke	Not being supported for reregistration.
Pears	1	Revoke	Not being supported for reregistration.

Commodity	Tolerance Listed Under 40 CFR (ppm)	Reassessed Tolerance (ppm)	Comment *[Correct Commodity Definition]*
Pecans	0.01	Revoke	Not being supported for reregistration.
Peppers	1	Revoke	Not being supported for reregistration.
Pineapple	1	Revoke	Not being supported for reregistration.
Plums (fresh prunes)	1	Revoke	Not being supported for reregistration.
Pumpkins	3	Revoke	Not being supported for reregistration.
Quinces	1	Revoke	Not being supported for reregistration.
Squash	3	Revoke	Not being supported for reregistration.
Strawberries	1	Revoke	Not being supported for reregistration.
Summer squash	3	Revoke	Not being supported for reregistration.
Tomatoes	3	Revoke	Not being supported for reregistration.
Tolerance To Be Proposed Under 40 CFR §180.133			
Barley, grain		0.005	
Barley, hay		0.02	
Barley, straw		0.005	
Corn, field, grain		0.005	
Corn, pop, grain		0.005	
Corn, sweet, kernel plus cob with husks removed		0.005	
Corn, , field, forage		0.05	
Corn, sweet, forage		0.05	
Corn, field, stover		0.05	A nature of the residue study for lindane residues resulting from seed treatment application to a cereal grain is required. The Agency will re-calculate the maximum theoretical dietary burden for livestock animals and re-evaluate the adequacy of the available animal feeding studies when the required nature of the residue data in plants have been received and evaluated.
Corn, pop, stover		0.05	
Corn, sweet, stover		0.05	
Oat, grain		0.005	
Oat, forage	None established	0.05	
Oat, hay		0.02	
Oat, straw		0.005	
Rye, grain		0.005	
Rye, forage		0.05	
Rye, straw		0.005	
Sorghum, grain, grain		0.005	
Sorghum, forage		0.05	
Sorghum, grain, stover		0.05	
Wheat, grain		0.005	
Wheat, forage		0.05	
Wheat, hay		0.02	
Wheat, straw		0.005	
Cattle, meat byproducts		0.01	

Commodity	Tolerance Listed Under 40 CFR (ppm)	Reassessed Tolerance (ppm)	Comment *[Correct Commodity Definition]*
Goat, meat byproducts		0.01	
Horse, meat byproducts		0.01	
Sheep, meat byproducts		0.01	
Cattle, meat		0.01	
Goat, meat		0.01	
Horse, meat		0.01	
Sheep, meat		0.01	
Milk		0.01	
Poultry, fat		0.01	

CODEX HARMONIZATION

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for lindane in/on various plant and animal commodities. The Codex MRLs are expressed in terms of gamma HCH (fat-soluble). With respect to tolerance expression, the Codex MRL and U.S. tolerance for lindane are presently in harmony. However, the nature of the residue in plants remains inadequately understood, and the HED's MARC may determine that additional lindane metabolites should be included in the U.S. tolerance expression.

A numerical comparison of the Codex MRLs and the corresponding **reassessed** U.S. tolerances resulting from seed treatment is presented in Table C. The established Codex MRLs and the recommended U.S. tolerances for Brussels sprouts, cabbage (Savoy), cabbages (head), cereal grains, lettuce (head), and radish are not in harmony presumably because of differences in good agricultural practices. Attempts to harmonize residue limits in animal commodities cannot be made at this time because of several residue chemistry data gaps.

Table C. Codex MRLs and applicable U.S. tolerances for lindane. Recommendations are based on conclusions following reassessment of U.S. tolerances (see Table B).

Codex		Reassessed U.S. Tolerance, ppm [1]	Codex Comments
Commodity, As Defined	MRL in mg/kg (Step)		
Apple	0.5 (CXL)	Revoke	Not being supported for reregistration.
Beans (dry)	1 (CXL) [2]	None established	Not being supported for reregistration.
Brussels sprouts	0.5 (CXL)	Revoke	Not being supported for reregistration.
Cabbage, Savoy	0.5 (CXL)	Revoke	Not being supported for reregistration.
Cabbages, Head	0.5 (CXL)	Revoke	Not being supported for reregistration.
Cacao beans	1 (CXL)	None established	Not being supported for reregistration.
Carrot	0.2 (CXL)	None established	Not being supported for reregistration.
Cauliflower	0.5 (CXL)	Revoke	Not being supported for reregistration.
Cereal grains	0.5 (CXL) [2]	0.005 ppm for the grains of barley, oats, rye, and wheat	The Agency will re-evaluate the cereal grain tolerances when the required nature of the residue data in plants have been received and evaluated.
Cherries	0.5 (CXL)	Revoke	Not being supported for reregistration.
Cocoa butter	1 (CXL)	None established	Not being supported for reregistration.
Cocoa mass	1 (CXL)	None established	Not being supported for reregistration.
Cranberry	3 (CXL)	None established	Not being supported for reregistration.
Currant, Red, White	0.5 (CXL)	None established	Not being supported for reregistration.
Eggs	0.1 (CXL)	None established	The Agency will re-calculate the maximum theoretical dietary burden for livestock animals and re-evaluate the adequacy of the available animal feeding studies when the required nature of the residue data in plants have been received and evaluated.
Endive	2 (CXL)	None established	Not being supported for reregistration.

Codex		Reassessed U.S. Tolerance, ppm [1]	Codex Comments
Commodity, As Defined	MRL in mg/kg (Step)		
Grapes	0.5 (CXL)	Revoke	Not being supported for reregistration.
Kohlrabi	1 (CXL)	Revoke	Not being supported for reregistration
Lettuce, Head	2 (CXL)	Revoke	Not being supported for reregistration.
Meat of cattle, pigs, and sheep	2 (CXL)	0.01 (cattle and sheep)	**See "Eggs"**
Milks	0.1 (CXL)	0.01	**See "Eggs"**
Pear	0.5 (CXL)	Revoke	Not being supported for reregistration.
Peas (pods and succulent = immature seeds)	0.1 (CXL)	None established	Not being supported for reregistration.
Plums (including prunes)	0.5 (CXL)	Revoke	Not being supported for reregistration.
Potato	0.05 (CXL)	None established	Not being supported for reregistration.
Poultry meat	0.7 (CXL)	None established	**See "Eggs"**
Radish	1 (CXL)	Revoke	Not being supported for reregistration.
Rape seed	0.05 (CXL)	None established	Not being supported for reregistration.
Spinach	2 (CXL)	Revoke	Not being supported for reregistration.
Strawberry	3 (CXL)	Revoke	Not being supported for reregistration.
Sugar beet	0.1 (CXL)	None established	Not being supported for reregistration.
Sugar beet leaves or tops	0.1 CXL)	None established	Not being supported for reregistration.
Tomato	2 (CXL)	Revoke	Not being supported for reregistration.

[1] Reassessed U.S. tolerances pending compliance by the registrants with the recommendations specified in "GLN 860.1200: Directions for Use" section of this Chapter.

[2] Postharvest treatment of the commodity.